

- inserting the device into the lumen of the lead with the flexible distal portion substantially entirely contained within the distal portion of the lead; feeding an introducer sheath along a predetermined path including at least the SVC and coronary os; inserting the distal portion of the lead into 5 the introducer sheath and advancing the lead until the distal portion of lead reaches the coronary sinus region; advancing the device relative to the lead to extend the flexible distal portion of the device from the aperture in the tip electrode; manipulating the steering knob on the proximal end of the main body of the device as necessary to maneuver 10 the flexible distal portion of the device into said implantation site; slidably advancing the lead over the device to move said electrode into place at the implantation site; retracting the device and removing the device from the lead; and retracting and removing the introducer sheath.

It will be seen that unlike the prior art, the lead body provides the 15 guide or delivery tool for the flexible distal portion of the device of the invention. It will also be appreciated that the device of the present invention has the advantage of greatly speeding up the process of lead implantation. It avoids both the relative inflexibility of a stylet and the awkwardness of using an unduly long guide wire yet it is designed for use 20 with a lead body designed for over-the-wire placement with all of the attendant advantages.

#### Brief Description of the Drawings

The foregoing and other objects, features and advantages of the 25 invention will be evident to those skilled in the art from the detailed description, below, taken together with the accompanying drawings, in which:

- FIG. 1 is a side view of a typical endocardial lead assembly for placement in a vessel in the coronary sinus region of the heart;
- 30 FIG. 2 is a side view of a stylet in accordance with the prior art;
- FIG. 3 is a side view of a guide wire in accordance with the prior art;

FIG. 4 is a side view of a device in accordance with a first embodiment of the present invention for placing a body implantable lead in the coronary sinus region of the heart;

5 FIG. 5 is a side view of a device in accordance with a second embodiment of the present invention;

FIG. 6 is a side view of the distal portion of a device in accordance with a third embodiment of the present invention;

10 FIG. 7 is a side view of the distal portion of a device in accordance with a fourth embodiment of the present invention;

FIG. 8 is a perspective view of the distal portion of a device in accordance with a fifth embodiment of the present invention;

15 FIG. 9 is a side view, partly in cross section, of the distal portion shown in FIG. 8;

FIG. 10 is a top view, partly in cross section, of the distal portion shown in FIG. 8;

FIG. 11 is a side view of the distal portion of a device in accordance with a sixth embodiment of the present invention;

FIG. 12 is a side view of an endocardial lead with the device of the invention in place therein preparatory to implantation of the lead; and

20 FIGS. 13-15 are perspective views of the anterior portion of the heart showing steps in the use of the device of the present invention.

#### Detailed Description of the Invention

It will be appreciated that for the sake of clarity, the dimensions and proportions of the devices shown in the drawings have been greatly exaggerated.

25 FIG. 4 shows a device 60, comprising a first embodiment of the invention, for directing and steering a body implantable lead, such as the lead body 12 of the lead assembly 10, into contact with heart tissue to be stimulated. Although the device 60 may be used to position a body implantable lead in the right chambers of the heart, that is, the right atrium and/or right ventricle, the device 60 has particular utility for placing a lead

transvenously within the coronary sinus region of the heart to perform 5  
pacing, sensing and/or defibrillation of the left atrium and/or left ventricle.  
As used herein, the phrase "coronary sinus region" refers to the coronary  
sinus, great cardiac vein, left marginal vein, left posterior ventricular vein,  
middle cardiac vein, and/or small cardiac vein or any other cardiac vein  
accessible via the coronary sinus.

The device 60 includes a relatively stiff main wire body 62 of  
stainless steel or like biocompatible, biostable material. By way of  
example and not limitation, the wire body 62 may have a diameter of .012  
10 to .018 inch, preferably about .014 inch. The main body of the device  
includes a proximal extremity 64 and a distal extremity 66.

The device 60 further comprises a steering knob 68 which, like the  
steering knob 46 on the prior art stylet 40 (FIG. 2) and unlike the  
releasable clamp 56 on the prior art guide wire 50 (FIG. 3), is secured,  
15 preferably permanently, to the proximal extremity 64 of the main wire  
body 62. The device 60 also includes a distal portion 70 comprising a wire  
coil 72 having a proximal end 74 affixed to the distal extremity 66 of the  
main wire body 62. In the embodiment of FIG. 4, the wire coil 72 has an  
outer diameter substantially the same as that of the main wire body 62 so  
20 as to form an isodiametric structure. The wire coil 72 is preferably made of  
stainless steel or a similar biocompatible, biostable alloy, in which case it  
is affixed to the distal extremity 66 of the main wire body 62 by means of a  
brazed joint or weld 76.

The wire coil 72 comprising the distal portion 70 of the device 60  
25 may be best described as a flexible or "floppy" element. By way of  
example and not limitation, this attribute may be provided by forming the  
wire coil 72 of No. 44 to 36 Brown and Sharpe gauge wire (.00198 to .005  
inch diameter, respectively) wound with a pitch of about 505 to about 200  
turns per inch, respectively. The wire coil 72 has a distal tip 78 that may  
30 be melted or fused to form a smooth leading surface. The steering knob  
68 secured to the proximal extremity of the main wire body 62 is used by  
the implanting physician to manipulate the main wire body 62 so as to